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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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(54) Title: BIOPSY APPARATUS AND METHOD

(57) Abstract: A biopsy apparatus for taking internal tissue samples with a non-concentric cutter and a vacuum source for taking at least one tissue sample. The first tube contains a needle tip and is rotated about a first longitudinal axis of rotation and includes a non-concentric vacuum passageway and a non-concentric second tube that is a cutter. A tissue port is formed within the first tube for taking tissue samples. A method is provided wherein the biopsy apparatus is positioned at least partially within a portion of tissue to be sampled. The needle is rotated to the desired directional angle for obtaining a tissue sample and a vacuum is applied to the tissue port. The non-concentric second tube translates longitudinally and rotates about a second longitudinal axis of rotation to cut tissue samples drawn into the tissue port of the with the assistance of the vacuum. The biopsy apparatus is capable of taking multiple sequential tissue samples.

BIOPSY APPARATUS AND METHOD

BACKGROUND

1. Technical Field

The present disclosure relates to instruments and methods used for obtaining tissue samples. More particularly, the present disclosure relates to minimally invasive biopsy instruments and methods for obtaining tissue samples.

2. Background of Related Art

It is often necessary to sample tissue in order to diagnose and treat patients suspected of having cancerous tumors, pre-malignant conditions and other diseases or disorders. Typically, in the case of suspected cancerous tissue, when the physician establishes by means of procedures such as palpation, x-ray or ultrasound imaging that suspicious conditions exist, a biopsy is performed to determine whether the cells are cancerous. Biopsy may be done by an open or percutaneous technique. Open biopsy removes the entire mass (excisional biopsy) or a part of the mass (incisional biopsy). Percutaneous biopsy on the other hand is usually done with a needle-like instrument and may be either a fine needle aspiration (FNA) or a core biopsy. In core biopsy, as the term suggests, a core or fragment tissue is obtained for histologic examination which may be done via frozen section or paraffin section.

The type of biopsy utilized depends in large part on the circumstances present with respect to the patient and no single procedure is ideal for all cases. Core biopsy, however, is extremely useful in a number of conditions and is being used more frequently.

Intact tissue from the organ or lesion is preferred by medical personnel in order to arrive at a definitive diagnosis regarding the patient's condition. In most cases only part of the organ or lesion need be sampled. The portions of tissue extracted must be indicative of the organ or lesion as a whole. In the past, to obtain adequate tissue from organs or lesions within the body, surgery was performed so as to reliably locate, identify and remove the

tissue. With present technology, medical imaging equipment such as stereotactic x-ray, fluoroscopy, computer tomography, ultrasound, nuclear medicine and magnetic resonance imaging, may be used. These technologies make it possible to identify small abnormalities even deep within the body. However, definitive tissue characterization still requires obtaining adequate tissue samples to characterize the histology of the organ or lesion.

The introduction of stereotactic guided percutaneous breast biopsies offered alternatives to open surgical breast biopsy. With time, these guidance systems have become more accurate and easier to use. Biopsy guns were introduced for use in conjunction with these guidance systems. Accurate placement of the biopsy guns was important to obtain useful biopsy information because only one small core could be obtained per insertion at any one location. To sample the lesion thoroughly, many separate insertions of the instrument had to be made.

Biopsy procedures may benefit from larger tissue samples being taken, for example, tissue samples as large as 10 mm across. Many of the prior art devices required multiple punctures into the breast or organ in order to obtain the necessary samples. This practice is both tedious and time consuming.

One further solution to obtain a larger tissue sample is to utilize a device capable of taking multiple tissue samples with a single insertion of an instrument. Generally, such biopsy instruments extract a sample of tissue from a tissue mass by either drawing a tissue sample into a hollow needle via an external vacuum source or by severing and containing a tissue sample within a notch formed on a stylet. Such devices generally contemplate advancing a hollow needle into a tissue mass and applying a vacuum force to draw a sample into the needle and hold the same therein while the tissue is extracted.

A continuing need exists for percutaneous biopsy apparatus and methods which can reliably extract adequate biopsy sample(s) with a single insertion of the biopsy instrument.

SUMMARY

A biopsy apparatus is provided that employs a non-concentric cutter in combination with separate vacuum lumen to create an effective tissue slicing mechanism that is capable of taking multiple sequential tissue samples. The separate vacuum lumen can be integral to the outer tube or an independent structure.

A biopsy method is provided wherein a hollow tubular needle with a tissue port and a non-concentric inner member with a cutting edge is at least partially positioned within a portion of tissue to be sampled. A vacuum is applied at the tissue port to augment tissue prolapse and the inner member is moved to sever a tissue sample. The tissue sample can then be retrieved by withdrawing the apparatus or additional sequential tissue samples can be obtained prior to the withdrawal of the apparatus from the patient.

The invention, together with attendant advantages, will be best understood by reference to the following detailed description of the invention when used in conjunction with the figures below.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the presently disclosed biopsy apparatus are described herein with reference to the drawings, wherein:

FIG. 1A is a perspective view with parts separated of the distal end of one embodiment of a biopsy apparatus constructed in accordance with the present disclosure;

FIG. 1B is a distal end view of the outer tube of the embodiment of FIG. 1 showing the vacuum passageway and non-concentric cutter passageway;

FIG. 2A is a perspective view of the distal portion of an alternative embodiment of the presently disclosed biopsy apparatus with a non-concentric vacuum tube within a non-concentric cutter in a first closed position;

FIG. 2B is a perspective view similar to FIG. 2A of the distal portion of an alternative embodiment of the presently disclosed biopsy apparatus with a non-concentric vacuum tube within a non-concentric cutter in a second open second position;

FIG. 2C is a perspective view of a second configuration of the biopsy apparatus with a non-concentric vacuum tube within a non-concentric cutter in a third position with

the inner tube in a closed position; and

FIG. 2D is a transverse cross-sectional view of the non-concentric vacuum tube and cutter detailing the different rotational axes and the rotational relationships of the vacuum tube, cutter, and outer tube.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Referring now in specific detail to the drawings in which like referenced numerals identify similar or identical elements throughout the several views, and initially to FIG. 1A, a preferred embodiment of a non-concentric cutter biopsy apparatus 100 (hereinafter referred to as "biopsy apparatus 100") includes a needle 10, an outer tube 20, and inner tube 30.

For purposes of clarity, only the details of the working distal ends 22, and 32 are illustrated in detail. Their respective proximal ends may be attached to a suitable handle or actuator to facilitate operation of biopsy apparatus 100. For example, biopsy apparatus 100 may include a housing wherein outer member 20 and inner member 30 are housed. The housing may include suitable known driving and actuating mechanisms. In one embodiment penetrating member may be rapidly movable into position at the target tissue location by a suitable drive mechanism, such as, for example, potential energy devices, drive motors, pneumatic devices, or any other suitable drive mechanism.

Needle 10 includes a proximal end with a mechanical retention mechanism 12 and a distal end with a tip 14. Retention mechanism 12 provides a mechanical interface between needle tip 14 and a distal end 22 of outer tube 20 that is configured to be easily snapped into position. In an alternative configuration needle 10 can be monolithically formed or integrally attached with outer tube 20.

Outer tube 20 includes tubular wall 21 that forms a distal end 22 and a proximal end (not shown). Tubular wall 21 defines a non-concentric vacuum passageway 26, a non-concentric cutter passageway 28, and a tissue port 25. Needle tip 14, distal end 22, and proximal end (not shown) define a concentric longitudinal axis of rotation "X." Outer tube 20 non-concentric passageway 28 defines a longitudinal axis of rotation "Y" that is parallel and aligned with "X" axis. Tissue port 25 contains a basket type opening with a floor 29

for retaining at least one tissue sample. Floor 29 also defines a plurality of holes 27 that are in fluid communication with passageway 26 and a vacuum source (not shown). Vacuum passageway 26 draws a vacuum from tissue port 25 through holes 27 that assists the taking of tissue samples. Outer tube 20 is preferably made of a medical grade plastic but could be constructed of any medical grade material.

Inner tube 30 includes a tubular wall 31 that forms a distal end 32 and a proximal end (not shown) that when positioned within outer tube 20 forms a longitudinal axis of rotation that is concentric with the longitudinal axis "Y" of passageway 28. Distal end 32 contains a cutting edge 33 for severing tissue samples. Inner tube 30 can be repositioned or sever tissue samples by translating longitudinally or translating longitudinally while rotating about the "Y" axis. Inner tube 30 is preferably made of a metal or a similar material that is capable of holding a sharpened knife type cutting edge 33 on distal end 32.

In FIG. 1B, one configuration of outer tube 20 includes non-concentric vacuum passageway 26 and non-concentric inner tube 30 passageway 28. Outer tube 20 rotates about the "X" axis. Inner tube 30 includes cutting edge 33 and rotates about the "Y" axis. This configuration provides a reliable vacuum to tissue sample interface that minimizes sealed connections within biopsy apparatus 100.

In operation biopsy apparatus 100 and its different embodiments and configurations disclosed herein, may be inserted by suitable known techniques, for example, by motor driver or spring fired mechanisms. Alternatively, biopsy apparatus 100 may be inserted manually. In either arrangement, biopsy apparatus 100 may be configured as a hand held apparatus or as part of a frame mounted device. An example of such a device is an image guided positioning apparatus such as a stereotactic imaging machine. Any suitable imaging modality may be used to guide biopsy apparatus to the target tissue.

Referring now to FIGS 1A and 1B, biopsy apparatus 100 when used operatively penetrates a tissue area and when at least partially positioned within the tissue to be sampled, biopsy apparatus 100 is then rotated about the "X" axis to position tissue port 25 to the desired tissue sample location. Inner tube 30 is then translated proximally from a first closed position covering tissue port 25 to an at least partially open second position exposing tissue port 25. A vacuum is applied and at least one tissue sample is taken by

translating or translating and rotating cutter distal end 32 in a distal direction along the "Y" axis to slice off a tissue sample into tissue port 25. Biopsy apparatus 100 also includes an external mechanism that indicates the orientation of tissue port 25 and depth of penetration into the tissue being sampled. Additional tissue samples can be taken by rotating and or translating outer tube 20 to reposition port 25. The withdrawal of biopsy apparatus 100 after at least one sequential sample is accomplished by closing tissue port 25 and withdrawing the biopsy apparatus 100.

Referring now to FIG. 2A, biopsy apparatus 200 includes a needle 210 with a needle tip 214, an outer tube 220, a non-concentric inner tube 230, and a non-concentric vacuum tube 240. Needle 210 is connected to distal end 222 of inner tube 230.

In FIG. 2B, outer tube 220 contains a distal end 222 and a proximal end 224 that define a longitudinal axis "X" of rotation. Proximal end 224 of outer tube 220 and inner tube 230 separate from distal end 222 of outer tube 220 by displacing along the longitudinal "X" axis, to at least partially expose a tissue port 225 that contains vacuum tube 240. Non-concentric inner tube or cutter 230 is a knife that contains a cutting edge 233 on its distal end 232 that translates and rotates about the "Y" axis. Vacuum tube 240 defines vacuum holes 247 that are in fluid communication, through tube 240, with a vacuum source (not shown). Vacuum tube 240 is rotatingly connected to distal end 222 of needle 210 and slidingly connected to proximal end 224.

In FIG. 2C, cutter 230 translates distally along the "Y" axis from within needle 20, from an open second position at least partially within proximal end 224 to a third closed position adjacent distal end 222 to sever a tissue sample.

In FIG. 2D, the axial relationship of non-concentric vacuum tube 240, non-concentric inner tube 230, and outer tube 220 are defined. Inner tube 230 rotates about longitudinal axis "Y" and vacuum tube 240 has a longitudinal axis of rotation "Z" that are both parallel to the "X" axis. Inner tube 230 and vacuum tube 240 can also rotate fixedly together about the "X" axis to position for tissue sampling. Vacuum tube 240 ports 247 are positioned opposite the sliding point of vacuum tube 240 with inner tube 230. Outer tube 220 includes an inner circumference 223. Inner tube or cutter 230 includes an inner circumference 233 and an outer circumference 235. Vacuum tube 240 contains an outer

circumference 245 and vacuum ports 247.

Referring once again to FIGS. 2A-2D, when piercing body tissue, outer tube 220 distal end 222 are connected with proximal end 224 to form a continuous outer tube 220 in a first position. Once adjacent or at least partially within the desired tissue sample area, inner tube 230 and vacuum tube 240 are rotated axially about the "X" axis together to position vacuum ports 247 towards the desired tissue sample location. Outer tube 220 proximal end 224, and inner tube 230, and are then translated longitudinally in a proximal direction from a first closed position to a second position that at least partially exposes vacuum tube 240. Tissue port 225 is defined by the opening between distal end 222 and the combination of proximal end 224 and inner tube 230. A tissue sample is taken by translating inner tube 230 longitudinally from a second position at least partially separated from distal end 222 to a first position wherein distal end 232 cutting edge 233 has sliced a tissue sample and is positioned adjacent distal end 222. In this process, a vacuum can be applied to augment the tissue cutting process. The translation of inner tube 230 can include a pure longitudinal translation or a combination of rotation about the "Y" axis and longitudinal displacements. The rotation of tube 230 about the "Y" axis also includes slidingly rotating inside circumference 233 of inner tube 230 against outer circumference 245 of non-concentric vacuum tube 240 while the outer circumference 235 of inner tube 230 slidingly rotates against the inner circumference of outer tube 223. The rotation of inner tube 230 is independent of needle 210. Biopsy apparatus 200 includes an external mechanism that indicates the orientation of tissue port 225 and depth of penetration into the tissue being sampled. Biopsy apparatus 200 is positioned for withdrawal after at least one sequential sample is taken by returning outer tube 220 to the first position.

Although the illustrative embodiments of the present disclosure have been described herein with reference to the accompanying drawings, it is to be understood that the disclosure is not limited to those precise embodiments, and that various other changes and modifications may be affected therein by one skilled in the art without departing from the scope or spirit of the disclosure. All such changes and modifications are intended to be included within the scope of the disclosure.

WHAT IS CALIMED IS:

1. A biopsy apparatus comprising:

a first tube having a tissue port, a distal end, and a proximal end, wherein the distal end and proximal end define a first longitudinal axis;

a second tube that includes a distal end with a cutting edge that is non-concentrically positioned at least partially within the first tube that can be positioned about a second longitudinal axis; and

a vacuum passageway positioned at least partially within the first tube and configured and adapted to draw a vacuum into the tissue port.

2. A biopsy apparatus according to claim 1, wherein the second longitudinal axis is spaced from the first longitudinal axis.

3. A biopsy apparatus according to claim 1, further comprising a plurality of holes formed along the length of the vacuum passageway and wherein the plurality of holes interconnect the vacuum passageway with the tissue port.

4. A biopsy apparatus according to claim 3, wherein the vacuum passageway is non-concentric with the first tube.

5. A biopsy apparatus according to claim 4, wherein the vacuum passageway is integrally formed within the first tube.

6. A biopsy apparatus according to claim 4, wherein the vacuum passageway is slidingly positioned at least partially within the second tube.

7. A method of taking internal tissue samples with a biopsy apparatus comprising the steps of:

piercing the patient with a biopsy apparatus;

positioning the needle at least partially within the tissue to be sampled by rotating the biopsy apparatus along a first longitudinal axis;

moving a non-concentric cutting tube, along a second longitudinal axis, from a first closed position to a second at least partially open position to expose a tissue port;

obtaining at least one tissue sample by drawing a vacuum into the tissue port and translating the non-concentric cutting inner tube from the at least partially open second position to the first closed position along the second longitudinal axis; and

withdrawing the biopsy apparatus while in the cutting inner tube is in the first closed position.

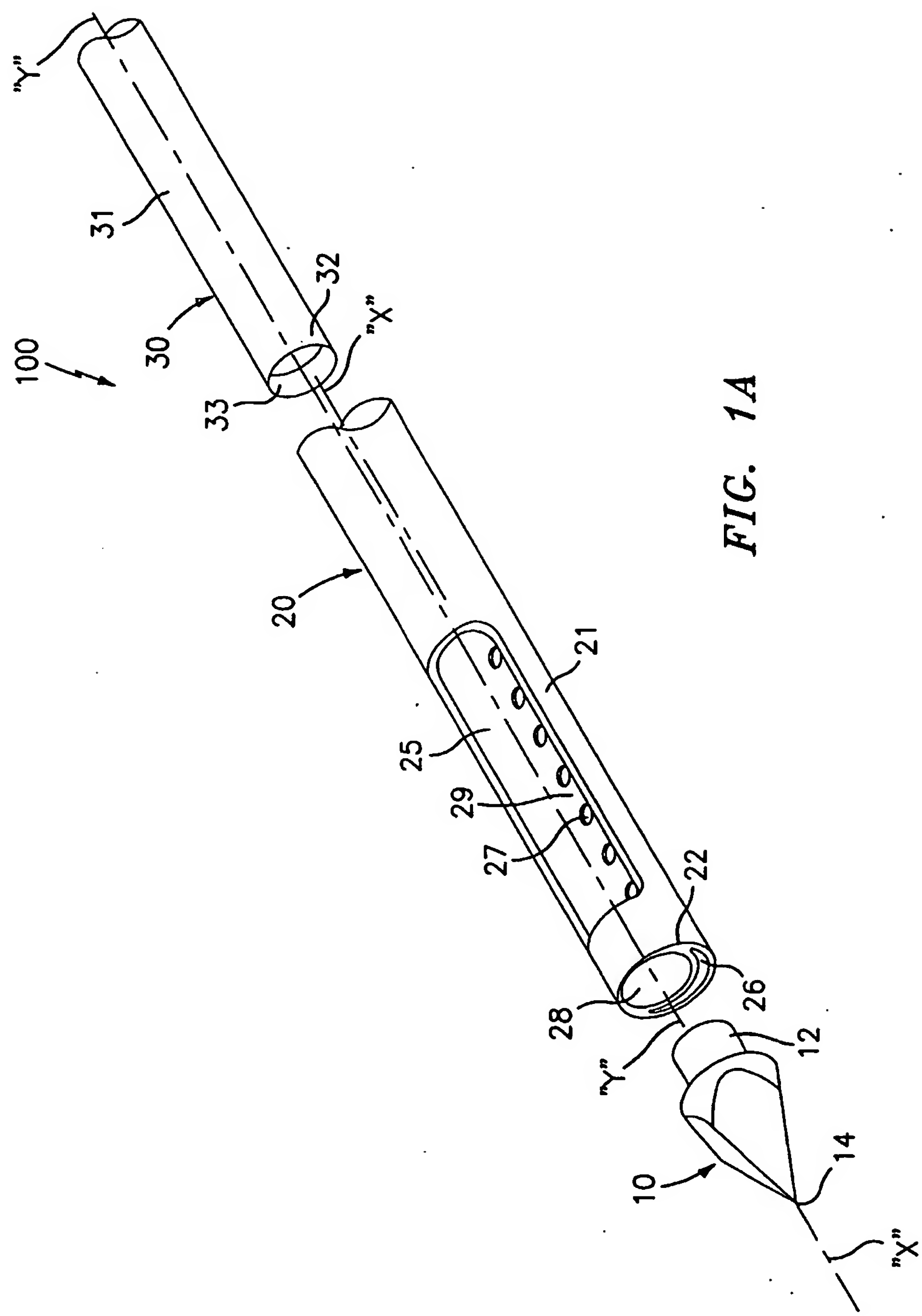

FIG. 1A

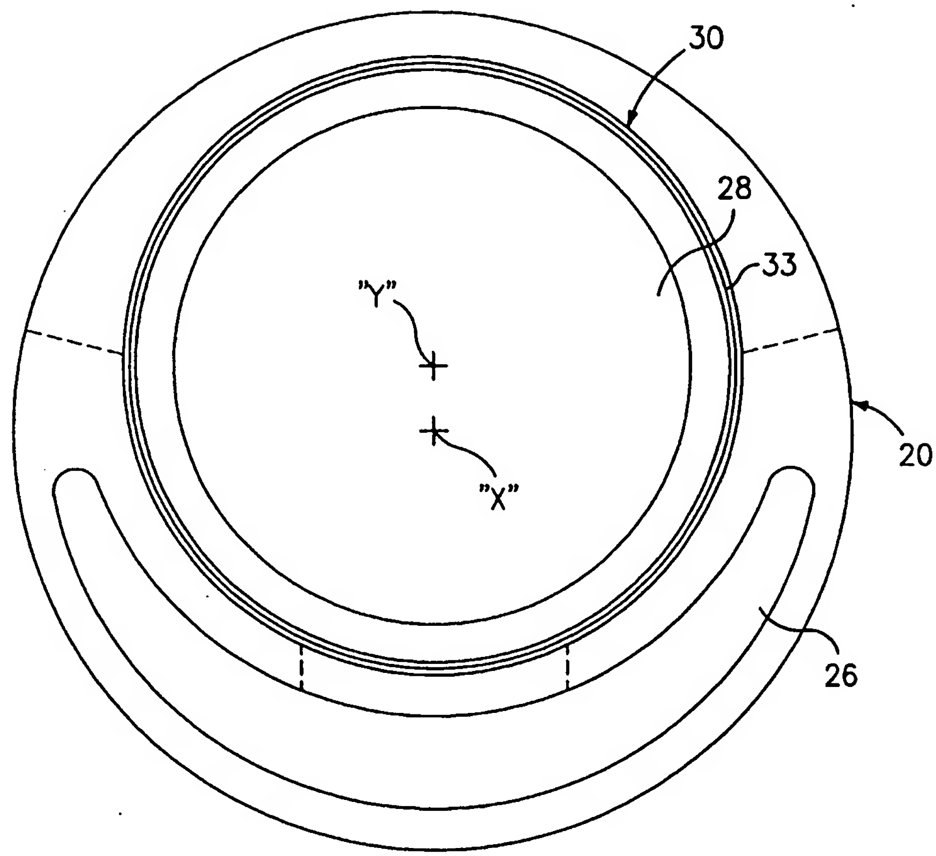

FIG. 1B

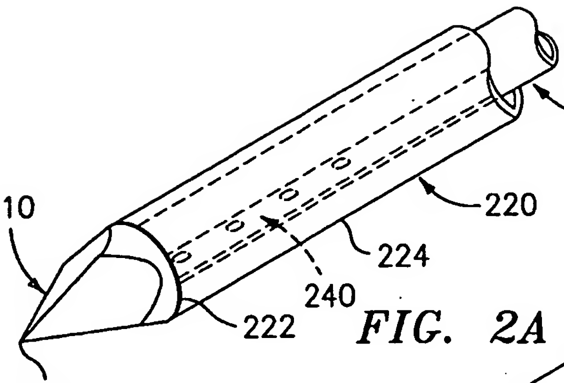

FIG. 2A

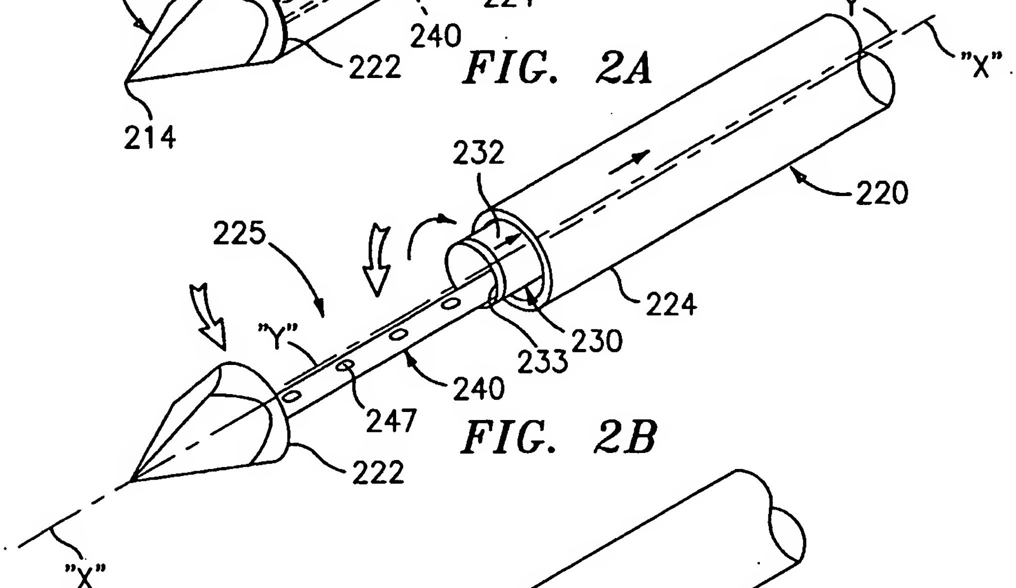

FIG. 2B

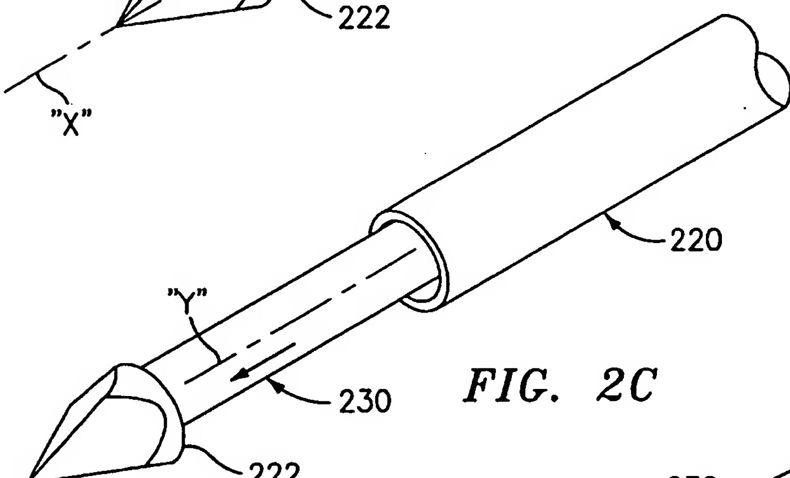

FIG. 2C

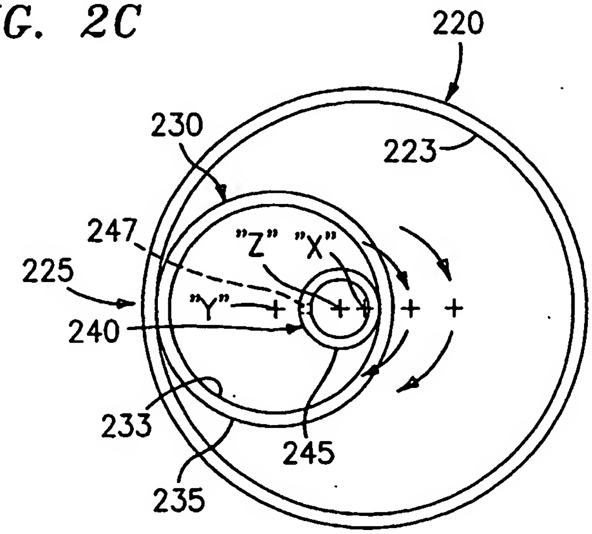

FIG. 2D

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(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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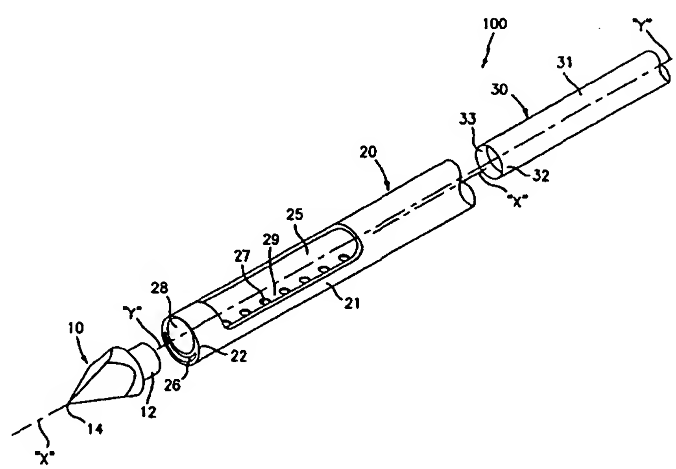
(54) Title: BIOPSY APPARATUS AND METHOD



(57) **Abstract:** A biopsy apparatus for taking internal tissue samples with a non-concentric cutter and a vacuum source for taking at least one tissue sample. The first tube contains a needle tip and is rotated about a first longitudinal axis of rotation and includes a non-concentric vacuum passageway and a non-concentric second tube that is a cutter. A tissue port is formed within the first tube for taking tissue samples. A method is provided wherein the biopsy apparatus is positioned at least partially within a portion of tissue to be sampled. The needle is rotated to the desired directional angle for obtaining a tissue sample and a vacuum is applied to the tissue port. The non-concentric second tube translates longitudinally and rotates about a second longitudinal axis of rotation to cut tissue samples drawn into the tissue port of the with the assistance of the vacuum. The biopsy apparatus is capable of taking multiple sequential tissue samples.

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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B10/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 00 30531 A (JONES MICHAEL ;LUBOCK PAUL (US); SHABAZ MARTIN (US); BURBANK FRED) 2 June 2000 (2000-06-02) page 10, line 1 - line 20; figure 2 page 13, line 19 - line 25; figure 3 ---	1-3
Y	US 5 944 673 A (PRIVITERA SALVATORE ET AL) 31 August 1999 (1999-08-31) column 6, line 51 -column 7, line 8; figure 2 ---	1-3
A	US 5 769 086 A (BURBANK FRED H ET AL) 23 June 1998 (1998-06-23) column 5, line 6 - line 17; figures 2-4 --- -/--	1,2,4,5

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
4 September 2002	11/09/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Ducreau, F

1

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 02/03279

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 850 373 A (DINGES HANS P ET AL) 25 July 1989 (1989-07-25) column 3, line 1 -column 4, line 16; figures 1,2	1,2
A	US 6 142 955 A (KLECHER CHRISTOPHER F ET AL) 7 November 2000 (2000-11-07) column 11, line 50 -column 12, line 6; figures 20-22	1,3

1

International application No.
PCT/US 02/03279

INTERNATIONAL SEARCH REPORT

Box I Observation where certain claim were found unsearchable (C ntinuati n of item 1 f first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 7
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

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PCT/US 02/03279

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0030531 A	02-06-2000	AU 1738200 A	13-06-2000
		EP 1130997 A1	12-09-2001
		WO 0030531 A1	02-06-2000
		US 2002111564 A1	15-08-2002
US 5944673 A	31-08-1999	NONE	
US 5769086 A	23-06-1998	CA 2239614 A1	12-06-1997
		EP 0939604 A1	08-09-1999
		JP 2001515372 T	18-09-2001
		WO 9720504 A1	12-06-1997
US 4850373 A	25-07-1989	AT 385890 B	25-05-1988
		AT 91487 A	15-11-1987
		CA 1293417 A1	24-12-1991
		DE 3782679 D1	24-12-1992
		DK 202688 A	14-10-1988
		EP 0243341 A2	28-10-1987
		ES 2036222 T3	16-05-1993
		FI 881634 A	14-10-1988
		JP 63279828 A	16-11-1988
		NO 881581 A	14-10-1988
US 6142955 A	07-11-2000	AU 728656 B2	18-01-2001
		AU 9491298 A	12-04-1999
		CA 2303814 A1	01-04-1999
		EP 1026992 A1	16-08-2000
		JP 2001517470 T	09-10-2001
		WO 9915079 A1	01-04-1999